

K061087

**510(k) Summary**  
**Honeywell HomMed Genesis OTC Monitor System**

JUN - 9 2006

Date: April 11, 2006

Consultant Contact: Tommie J. Morgan, Ph.D., President  
Morgan Consultants Inc.  
2018 North Durham Drive  
Houston, TX 77008  
713.880.5111 Voice or 713.880.3494 Fax

Company: Michael Leigh, Director Regulatory/Quality  
Honeywell HomMed, LLC  
3400 Intertech Drive, Suite 200  
Brookfield, WI 53045  
262.252.5794 Voice or 262.252.6119 Fax

Trade Name: Honeywell HomMed Genesis OTC Monitor

Common Name: Vital Signs Monitor

Classification Name: Cardiovascular and Respiratory Devices, Class II

Product Code: NIBP Measurement System, DXN

Predicate Device(s): HomMed Genesis Patient Monitor System K040799

Device Description: The Honeywell HomMed Genesis OTC Monitor System is a vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, and weight. The Genesis OTC Monitor has four serial ports available for external options. The Genesis OTC Monitor acquires vital signs data and displays it. The data can also be transmitted via the communication system to a central viewing station.

Indications for Use: *The Honeywell HomMed Genesis OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, and weight. Data from optional commercial stand-alone products extend Genesis OTC Monitor's measurement capabilities. Data from the Genesis OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Genesis OTC Monitor is not intended for emergency use or real-time monitoring.*

Intended Use: The Honeywell HomMed Genesis OTC is the remarketing of a previously approved product for OTC use. It is intended for personal use where use of the system allows retrospective review of certain physiological functions. The Genesis OTC collects vital signs data (including noninvasive blood pressure, pulse rate, and weight plus data from optional add-on devices) then can transmit the data to a central viewing station via a communication network. Genesis OTC Monitor is intended for use with adult and pediatric patients over twelve years of age.

Technology: Genesis OTC Monitor employs the same technologies as the predicate device, HomMed Genesis Patient Monitor System, K040799.

The Honeywell HomMed Genesis OTC Monitor complies with the following voluntary standards:

- EN 60601-1 Medical Electrical Safety
- IEC 601-1-2 EMC Compliance
- ISO 10993-5,10-11 Biocompatibility

**Test Summary:** The Honeywell HomMed Genesis Monitor System (Genesis OTC and its predicate Genesis) utilized within the environments for which it is marketed performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices. Completed EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The test results demonstrated that the Genesis is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

**Conclusion:** It is the Honeywell HomMed position that the results of these evaluations demonstrate the Genesis OTC Monitor is as safe, as effective and performs as well as the legally marketed predicate device, HomMed Genesis Patient Monitor.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 9 2006

Honeywell HomMed, LLC  
c/o Tommie J. Morgan, Ph.D.  
President  
Morgan Consultants Inc.  
2018 North Durham Drive  
Houston, TX 77008

Re: K061087

Trade Name: Honeywell HomMed Genesis OTC Monitor  
Regulation Number: 21 CFR 870.2910  
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver  
Regulatory Class: II (two)  
Product Code: DRG  
Dated: April 12, 2006  
Received: April 18, 2006

Dear Dr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

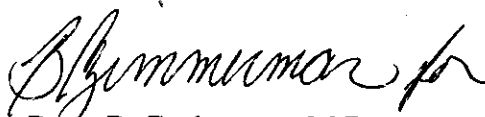
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K061087

Device Name: Honeywell HomMed Genesis OTC Monitor

### Indications For Use:

The Honeywell HomMed Genesis OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, and weight. Data from optional commercial stand-alone products extend Genesis OTC Monitor's measurement capabilities. Data from the Genesis OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Genesis OTC Monitor is not intended for emergency use or real-time monitoring.

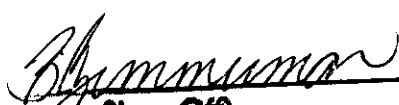
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off  
Division of Cardiovascular Devices  
510(k) Number K061087